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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LUSTUSKY, SARA	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,586	PATRICK ET AL.	
	Examiner	Art Unit	
	Sara Lustusky	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 and 31-33 is/are rejected.

7)☒ Claim(s) 30 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 11/14/03 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 05/14/04,06/29/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because they include shading not in accordance with 37 CFR 1.84(m) and lead lines without corresponding reference characters.

2. The drawings are further objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: (40) as seen in Figures 4A and 5, and because they do not include the following reference sign(s) mentioned in the description: (41) as described in line 21 of page 9.

3. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by

the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-3, 6-7, 11-19, 23, 26, 29 and 31** are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (US 6419692 B1).

6. Yang et al. teaches a drug eluting brachytherapy device (as seen in Figures 4 and 5), comprising:

a. an insertion member (60) having a proximal portion, a distal portion, and at least one lumen extending therethrough (as seen in Figure 5);

b. an expandable surface member (62) mated to the distal portion of the insertion member (60) and defining a spatial volume therein (as seen in Figure 5); and

c. a treatment agent (30) releasably mated with the expandable surface member (62) (as described in lines 2-10 of column 3);

d. wherein at least a portion of the treatment agent (30) is delivered to adjacent tissue (54, 56) when the brachytherapy device is positioned within a tissue cavity (as described in lines 2-10 of column 3);

e. wherein the expandable surface member (62) is a fluid retaining expandable surface member, whereby expansion is caused by a fluid and retained during the procedure (as described in lines 42-59 of column 6);

f. wherein the treatment agent (30) is nonradioactive (as described in lines 10-27 of column 3);

g. wherein the treatment agent (30) is disposed or coated on at least a portion of the outer surface of the expandable surface member (62) or over the entire outer surface of the expandable surface member (as described in lines 60-66 of column 6 and in claim 1) ;

h. wherein the expandable surface member (62) includes a first surface adapted for positioning against a tissue surface (54, 56);

i. wherein the treatment agent (30) is disposed only on the first surface of the expandable surface member (62);

j. wherein the treatment agent (30) is selected from the group consisting of, an anti-neoplastic agent, an anti-angiogenesis agent, an immunomodulator, an immunotherapeutic agent, an antibiotic or combinations thereof (as described in lines 7-27 of column 3, lines 6-41 of column 5 and in Claims 1 and 4-5);

k. wherein the treatment agent (30) is mixed with a binding agent (as described in lines 19-27 of column 3) that can be a bioresorbable polymeric binding agent (as described in lines 45-56 of column 2); and

l. wherein the expandable surface member (62) is constructed of a material permeable to the treatment agent (as seen as layer 30 in Figure 5);

m. wherein the drug eluting brachytherapy device is positioned within a tissue cavity and the treatment agent (30) is delivered to the tissue (54, 56) surrounding the tissue cavity (as seen in Figures 4 and 5);

n. wherein more than one treatment agent (30) is disposed on the expandable surface member (62) (as described in lines 26-41 of column 5);

o. wherein the tissue cavity is a naturally occurring cavity (as described in lines 37-41 of column 2).

7. **Claims 1-9, 11-13, 16, 18-22, 24-26 and 31-33** are rejected under 35 U.S.C. 102(b) as being anticipated by Tam et al. (US 6458069 B1).

8. Tam et al. teaches a drug eluting brachytherapy device and a method of using the device (as seen in Figures 4 and 5), comprising:

a. an insertion member (18) having a proximal portion (20), a distal portion (21), and at least one lumen extending therethrough (as seen in Figures 2-7);

b. an expandable surface member (22, 26, 54) mated to the distal portion (21) of the insertion member (18) and defining a spatial volume therein (as seen in Figures 4-6); and

c. a treatment agent is mixed with a binding agent (as described in lines 1-5 of column 7) and is releasably mated with the expandable surface member (22, 26, 54) (as described in lines 56-67 of column 17 and in lines 51-62 of column 22);

d. wherein the expandable surface member (22, 26, 54) is a fluid retaining expandable surface member (22, 26, 54) similar to those commonly used in the art, with a first surface adapted for positioning against a tissue surface (as described in lines as seen in Figures 4-6);

e. wherein there is more than one treatment agent including radioactive and nonradioactive agents (as described in lines 56-67 of column 17 and in lines 51-62 of column 22);

f. wherein at least a portion of the treatment agent is delivered to adjacent tissue when the brachytherapy device is positioned within a tissue cavity (as described in lines 28-38 of column 19 and in the abstract);

g. wherein the treatment agents are coated or disposed on all or a portion of the outer surface and the inner surface of the expandable surface member (22, 26, 54) (as described in lines 56-67 of column 17 and in lines 51-62 of column 22) such that there may be more than one layer of treatment agent disposed on the surface of the expandable surface member (22, 26, 54);

h. wherein different treatment agents are disposed in different layers (as seen in Figures 4-7 and 9-9A);

i. wherein a radiation source (10) is disposed outside of the expandable surface member or in an alternate embodiment is disposed within the expandable surface member (22, 26, 54) (as described in lines 51-59 of column 22);

j. wherein the expandable surface member (22, 26, 54) is constructed of a material permeable to radioactive treatment agents as it is not made of shielding material and therefore the radiation is permeable through the device and into the surrounding tissue creating a three-dimensional isodose profile that is substantially similar in shape to the expandable surface member (22, 26, 54);

k. wherein the expandable surface member includes portions that are inherently permeable to fluids within the body (as described in lines 56-66 of column 17) and portions that are nonpermeable to fluids within the body in which the radioactive treatment agents are mated with only the nonpermeable portions (as described by the embodiment in lines 10-12 of column 26);

l. wherein more than one type of radioactive treating agent capable of permeating through the walls of the expandable surface member (22, 26, 54) is disposed within the expandable surface member (22, 26, 54) (as described in lines 4-8 and 30-45 of column 23);

m. wherein a fluid delivery path (58) capable of delivering a treatment agent extends through the catheter body (52) into the spatial volume within the expandable surface member (54), and out through the expandable surface member (54) (as described in lines 28-38 of column 19) (as seen in Figure 5);

n. wherein using the brachytherapy device comprises positioning the brachytherapy device within a tissue cavity and delivering a treatment agent to tissue surrounding the tissue cavity (as described in lines 14-24 of column 20);

o. wherein the tissue cavity may be a mechanically formed or a naturally occurring cavity selected from the group consisting of the esophagus, the urethra and the ureters (as described in lines 14-24 of column 20).

9. **Claims 1-3, 6-7, 13-14, 16-18, 26, 28 and 31** are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (US 6409716 B1).

10. Sahatjian et al. teaches a method of delivering a treatment material, comprising:

a. providing a drug eluting brachytherapy device having an insertion member or catheter body member (3) with a proximal portion and a distal portion (as seen in Figures 1-2A) and at least one lumen,

b. an expandable surface member (4) defining a spatial volume,

c. a treatment agent (8, 44) releasably mated with a first surface of the expandable surface member (4);

d. positioning the brachytherapy device within a tissue cavity wherein the first surface is positioned against a tissue surface (as described in lines 15-29 of column 3), and

e. delivering the treatment agent (8, 44) to tissue surrounding the tissue cavity (as described in lines 52-67 of column 1);

f. wherein the treatment material (8, 44) is a chemotherapy drug (as described in lines 63-67 of column 13 and in lines 1-11 of column 14);

g. wherein the expandable surface member is fluid retaining (as described in lines 52-54 of column 2);

h. wherein the treatment agent is nonradioactive (as described in lines 1-14 of column 3);

i. wherein the treatment agent is disposed or coated on the outer surface of the expandable surface member (as described in the abstract);

j. wherein the treatment agent is mixed with a bioresorbable polymeric binding agent (as described in the abstract);

k. wherein the tissue cavity may be naturally occurring (as described in the abstract and in lines 1-3 of column 2).

11. **Claims 1-3, 6-7, 10, 13, 16, 18-21, 26, 31, 32, 33** are rejected under 35 U.S.C. 102(b) as being anticipated by Shapland et al. (US 5286254).

12. Shapland et al. teaches a drug eluting brachytherapy device and method of using comprising:

a. an insertion member having a proximal portion, a distal portion, and at least one lumen extending therethrough and an expandable surface member mated to the distal portion of the insertion member and defining a spatial volume therein (as seen in Figures 1-4 and described in claims 1, 7 and 12);

b. a treatment agent mixed with a binding agent that is releasably mated with the expandable surface member (as described in lines 1-12 of column 9);

c. wherein at least a portion of the treatment agent is delivered to adjacent tissue when the brachytherapy device is positioned within a tissue cavity (as described in lines 5-10 of column 3);

d. wherein the expandable surface member is a fluid retaining expandable surface member (as described in lines 31-38 of column 8);

e. wherein the treatment agent is nonradioactive (as described in Table 1 of column 11);

f. wherein the treatment agent is disposed or coated on the outer surface and is dispersed within a sidewall of the expandable surface member (as described in lines 1-12 of column 9);

g. wherein a second treatment agent capable of permeating through the walls of the expandable surface member is disposed within the expandable surface member (as described in lines 44-53 of column 2);

h. wherein a fluid delivery path for the delivery of a second treatment agent extends through the catheter body member into the spatial volume within the expandable surface member and out through the permeable expandable surface member (as described in lines 21-30 of column 8);

i. wherein the tissue cavity may be naturally occurring and is selected from the group consisting of the bladder, the urethra and the ureters, or may be mechanically formed (as described in lines 29-38 of column 2).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. **Claim 27** is rejected under 35 U.S.C. 103(a) as being unpatentable over Tam et al. (US 6458069 B1) as applied to claim 26 above, in view of Smith et al. (US 5422926).

15. Tam et al. teaches a method of delivering a treatment material comprising providing a drug eluting brachytherapy device having a catheter body member, an expandable surface member and a treatment agent releasably mated with the expandable surface member, as described above, wherein the brachytherapy device is positioned within a tissue cavity and the treatment agent is delivered to the tissue surrounding the cavity.

16. While Tam et al. teaches that the treatment agent may be delivered to areas either naturally occurring or surgically created that may benefit from the treatment agent (as described in lines 14-24 of column 20), the cavity formed after a lumpectomy procedure is not expressly taught.

17. Smith et al. teaches a method of using a catheter to deliver a treatment agent to a tissue cavity created from a lumpectomy procedure (as described in the abstract and in lines 56-63 of column 16).

18. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a method similar to that of Tam et al. to treat a tissue cavity created from a lumpectomy procedure similar to the method of Smith et al. in order to treat the surgical site and reduce the risk of reoccurrence of the removed tumor.

Allowable Subject Matter

19. **Claim 30** is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. Regarding claim 30, none of the prior art of record teaches or fairly suggests a method of delivering a treatment material comprising providing a drug eluting brachytherapy device having a catheter body member, an expandable surface member defining a spatial volume and a treatment agent releasably mated with the expandable surface member, positioning the brachytherapy device within a tissue cavity and delivering the treatment agent to tissue surrounding the tissue cavity, wherein more than one treatment agent is disposed on the expandable surface member

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shaw et al. (US 6918869) teaches a brachytherapy device that administers therapeutic agents to body tissues.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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